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P.O. Box 16446			HOLLM, JONATHAN A	
Arlington, VA 22215				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,940

Applicant(s)

GLOBERMAN, OREN

Examiner

JONATHAN A. HOLLM

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-43 and 58-79 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 20, 31-33 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12-19, 21-30, 34-43, 58-64 and 66-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2010 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06/01/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The Amendment filed 3 August 2010 has been entered. **Claims 1-10, 12-43, and 58-79** are pending in the application with **claims 7-10, 20, 31-33, and 65** being withdrawn from further consideration. The previous objections to the claims and rejections of claims under 35 U.S.C. 112, second paragraph are withdrawn in light of Applicant's amendments to the claims. Response to applicant's arguments can be found at the end of this office action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 1 June 2010 was filed after the mailing date of the non-final Office Action on 3 May 2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

3. The drawings were received on 3 August 2010. These drawings are acceptable.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore the limitations:

the extensions extending axially away or axially towards the body prior to moving apart of the anchor points (claims 20-21); and

the at least two hinges being bendable elements with no specific bending points defined thereon (claim 75)

must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. **Claims 1 and 78** are objected to because of the following informalities:

In **claim 1**, the phrase "defined on said at least one of" (line 6) should read - - defined on at least one of - -.

In **claim 78**, the phrase "a plurality of elongated extensions from said body" (line 6) should read -- a plurality of elongated extensions extending from said body --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claim 79** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. **Claim 79** recites the limitation "said two hinges" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 1-6, 12-19, 21-30, 34-38, 58-60, 64, 66-69, 71-72, and 74-77** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al (US Patent Number 6,325,826) in view of Shanley (US Patent Number 6,293,967) and Vargas et al (US Patent Number 6,428,550).

Vardi et al discloses a stent including a cylindrical body sized and shaped to be implanted in a vascular bifurcation and defining at least two implant points that move relative to each other, an aperture defined in a side of the expandable cylindrical body and designed for allowing passage to a side branch, at least two elongate extensions adjacent the aperture and configured to be extended away from the body into a side vessel, and a bridge coupling at least two of the extensions (see annotated figure 10 below); the extensions being capable of extending axially toward the body prior to expansion of the body; the bridge being defined at an end of the extensions and deformable; the extensions defining a flared section of the stent; the flared section being defined on a side of the stent; the flared section capable of having an axis generally perpendicular to an axis of the stent; the flared section being generally cylindrical; the stent and flared section being mesh; and the extensions facing each other across the aperture.

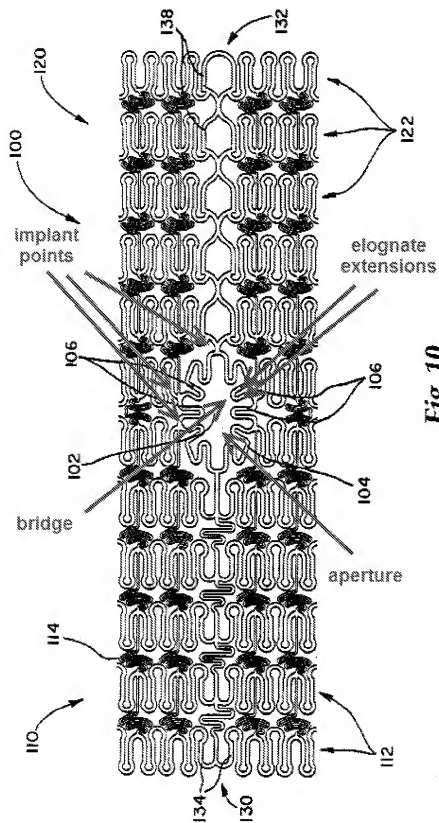


Fig. 10

The device of Vardi et al is not explicitly disclosed with at least two hinges defined on at least one of said extensions at least two of which have different preferred bending directions. Shanley teaches providing at least two hinges on an extension having different bending directions (see fig 3e). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Vardi et al to include at least two hinges defined on at least one of the extensions, as taught by Shanley, since Shanley teaches that such a configuration allows for more controlled expansion characteristics of the elongate members (column 6, lines 29-54).

The modified device of Vardi et al in view of Shanley is not explicitly disclosed with the hinges being defined on at least one of the extensions to allow a flaring of the at least one extension as an outcome of deformation of the body. Vardi et al teach the extensions being flared out by a balloon (see figure 13f). Vargas et al teach configuring hinges on elongate extensions to allow for flaring of the at least one extension as an outcome of deforming a cylindrical body (i.e., without the use of a balloon to cause the flaring; see figures 3-4; column 4, line 54 - column 5 line 19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Vardi et al in view of Shanley to configure the hinges to allow for a flaring of at least one extension upon deformation of the body, in view of Vargas et al, in order to simplify delivery of device by obviating the need for a balloon to flare the extension in a branch vessel. The hinges of the modified device of Vardi et al in view of Shanley and Vargas et al cooperate with the bridge to bend the elongate extensions in a direction

with a component perpendicular to a device plane of the body (i.e., into a branch vessel of a bifurcation).

Regarding **claims 2-3 and 5-6**, Shanley teaches each of the extensions including a plurality of hinges; the hinges of one extension being a mirror of hinges on another, coupled extension; at least one of the plurality of hinges having a bending direction different from a corresponding hinge on a second, coupled extension (see figure 4a); and at least one of the hinges having a resistance to bending different from a corresponding hinge on a second extension (column 7, line 45 – column 8, line 65);.

Regarding **claim 4**, the modified device of Vardi et al in view of Shanley and Vargas et al is not explicitly disclosed with the plurality of hinges on one extension having different axial locations than corresponding hinges on a second, coupled extension. However, Shanley teaches that the positions of the hinges may be altered to better suit a stent design (column 8, line 66 – column 9, line 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made modify the device of Vardi et al in view of Shanley and Vargas et al to have the hinges on one extension have different axial locations than corresponding hinges on a second, coupled extension, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Regarding **claim 12**, the hinges of the modified device of Vardi et al in view of Shanley and Vargas et al are arranged to bend at least one of said extensions at at least two points, in different directions.

Regarding **claims 13-16**, the modified device of Vardi et al in view of Shanley and Vargas et al discloses the claimed invention except for the hinges being arranged to bend the extensions to a specific range of angles. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vardi et al in view of Shanley and Vargas et al to have the hinges arranged to bend the extensions to an angle within the specified range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding **claims 17-19 and 76**, Vargas et al teach hinges being formed of cuts, weakenings, and bores (see figure 13; column 8, lines 10-21).

Regarding **claims 23-25 and 77**, Shanley teaches the bridge being more resistant to bending than the hinges and the hinges being plastically deformable (column 4, lines 43-47; the bridge taught by Shanley is bendable).

Regarding **claim 26**, the modified device of Vardi et al in view of Shanley and Vargas et al discloses the claimed invention except for the number of hinges being within a specific range. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Vardi et al in view of Shanley and Vargas et al to have the specified number of hinges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding **claim 60**, Shanley teaches the stent being structured such that parts of the extensions deform and parts do not deform (column 4, lines 37-52).

Regarding **claim 64**, Shanley and Vargas et al teach the hinges being parts of struts of the stent.

Regarding **claim 75**, Shanley teaches the hinges being bendable elements with no specific bending points defined on them (see figure 3D).

11. **Claim 70** is rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al (US Patent Number 6,325,826) in view of Shanley (US Patent Number 6,293,967) and Vargas et al (US Patent Number 6,428,550), as applied to claim 66 above, and further in view of Globerman et al (US Patent Number 6,402,777).

The device of Vardi et al in view of Shanley and Vargas et al is not explicitly disclosed with at least one of the extensions including a radio-opaque marker that extends away from the body with the extension. Globerman et al teach a stent with a radio-opaque marker attached to and capable of moving with an extension during expansion of a stent (see figures 1, 2, and 8-9). It would have been obvious for a person having ordinary skill in the art at the time of the invention to modify the device of Vardi et al in view of Shanley and Vargas et al to have at least one of the extensions include a radio-opaque marker that extends away from the body with the extension in view of Globerman et al, since Globerman et al teach that such a configuration allows a stent to be viewed during a procedure in order to assure proper placement of the stent (column 2, lines 15-23).

12. **Claims 39-43 and 61-63** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al (US Patent Number 6,325,826) in view of Vargas et al (US Patent Number 6,428,550).

Vardi et al teach a method of distorting a cylindrical stent structure having at least two extensions coupled at a point thereof and sized and shaped to be placed in a vascular bifurcation including changing the relative position of two points on said extensions (the implant points (see annotated figure 10 above) are moved relative to each other during inflation of the delivery balloon) that are distanced from the coupling point (see figures 13a-d), but is disclosed with using a balloon to bend the extension instead of transforming, using a plurality of pre-defined hinges, tension forces applied by said changing into forces that bend said structure in a plane outside of a plane defined by said changing. Vardi et al teach transforming, using a plurality of pre-defined hinges, tension forces applied by changing the relative position of points on extensions coupled to each other into forces that bend the extensions outside of a plane defined by the changing (i.e., without the use of a balloon; see figures 3-4; column 4, line 53 – column 5, line 9). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method of Vardi et al to transform, via a plurality of hinges, tension forces applied by said changing into forces to bend said extensions in a plane outside of a plane defined by the changing, in view of Vargas et al, in order to simplify delivery of device by obviating the need for a balloon to flare the extension in a branch vessel.

Regarding **claim 41**, Vardi et al teach the changing being applied by radially expanding the cylindrical stent structure.

Regarding **claims 42-43**, Vardi et al disclose transforming comprising flaring out extensions including a change in angle to more than 50 degrees relative to an axis of the cylinder (see figure 13f).

Regarding **claim 61**, Vardi et al discloses two extensions facing each other.

Regarding **claim 62**, Vardi et al disclose the extensions being extended into a side branch of a vessel bifurcation.

Regarding **claim 63**, Vargas et al disclose the transforming comprising deforming parts of the extensions and not deforming other parts of the extensions.

13. **Claim 73** is rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al (US Patent Number 6,325,826) in view of Vargas et al (US Patent Number 6,428,550).

Vardi et al disclose a method of deploying a stent including guiding an expandable cylindrical body to a vessel bifurcation, expanding the expandable cylindrical body, and extending away at least two extensions of the expandable body (see figures 13a-f). The method of Vardi et al teaches extending the at least two extensions by inflating a balloon instead of by expanding the body. Vargas et al teach extending extensions away from a cylindrical body by expanding a cylindrical body (i.e., without the use of a balloon to cause the extending; see figures 3-4; column 4, line 53 – column 5, line 19). It would have been obvious to a person having ordinary skill in the

art at the time of the invention to modify the method of Vardi et al to have the extending occur via expanding the body, in view of Vargas et al, in order to simplify the delivery of the stent by obviating the need for a balloon to extend the extensions into a branch vessel.

14. **Claims 78 and 79** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vardi et al (US Patent Number 6,325,826) in view of Vargas et al (US Patent Number 6,428,550).

Vardi et al discloses a stent for a bifurcation of a blood vessel including a expandable body having first (main body) and second parts (adjacent the aperture) joined to form a unitary structure, having a longitudinal axis and a surrounding surface, and defining at least two implant points that move relative to each other, and a plurality of elongate extensions each fixed to one implant point and having different preferred bending directions (see annotated figure 10 below).

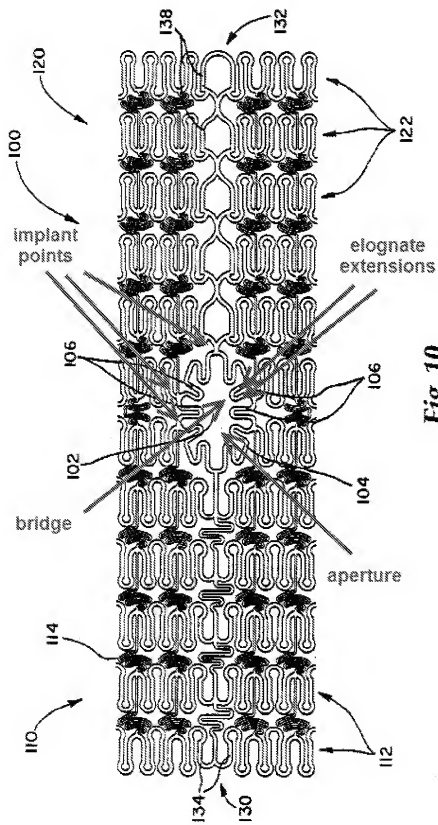


Fig. 10

The device of Vardi et al is disclosed with at least one of the extension moving out of the surface of the body and becoming oriented at an angle to the longitudinal axis of the body corresponding to the angle of the bifurcation (see at least figures 9 and 13a-h), but is not disclosed with the extension movement occurring upon an expansion force expanding the first part of the body outward. Vardi et al teach the extensions being flared out by a balloon (see figure 13f). Vargas et al teach configuring hinges on elongate extensions to allow for flaring of the at least one extension as an outcome of deforming a cylindrical body (i.e., without the use of a balloon to cause the flaring; see figures 3-4; column 4, line 54 - column 5 line 19). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Vardi et al to configure the extensions to move upon deformation of the body, in view of Vargas et al, in order to simplify delivery of device by obviating the need for a balloon to flare the extension in a branch vessel.

Response to Arguments

15. Applicant's arguments filed 3 August 2010 have been fully considered but they are not persuasive.
16. Applicant's amendment is not sufficient to overcome the objection to the drawings with respect to the subject matter of claims 20 and 21. The *drawings* do not show every feature of the inventions specified in these claims; therefore, the objection is maintained.

17. Applicant has not addressed the objection to the drawings with respect to the subject matter of claim 75. It is maintained that the drawings do not show every feature of the invention specified in this claim; therefore, the objection is maintained.

18. Regarding Applicant's arguments concerning the combination of the Vardi et al , Shanley, and Vargas et al references:

The Examiner respectfully disagrees with Applicant's assertion that the device of Vardi et al does not have a part that flares/expands out of the device plane of the body. The extensions noted in annotated figure 10 of Vardi et al (see above) extend into a side branch of a bifurcation to support the bifurcation point (see figures 13f-h; column 9, line 52 – column 10, line 19; column 11, lines 59-67).

In response to applicant's argument that Vargas et al is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Vargas et al is in the field of applicant's endeavor (implantable blood vessel support devices) and is reasonably pertinent to the particular problem with which the applicant is concerned (e.g., expansion of portions of an implantable medical device outside of a plane of the medical device). As such, Vargas et al qualifies as analogous art.

The Examiner respectfully disagrees with Applicant's assertion that the teachings of Vargas et al are not applicable to a stent. As the stent of Vardi et al and the

anastomosis device of Vargas et al are both sized and configured for placement within a patient's vasculature and the main bodies of the devices are radially expanded within the patient's vasculature in a similar manner (e.g., via a balloon), one of ordinary skill in the art would recognize that the mechanisms for expansion of different portions of the devices may be applied to one another.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As Vardi et al explicitly disclose extensions flaring out of the plane of a stent body into a side branch vessel (see figures 13f-h) and Vargas et al teach flaring out of extensions in response to expansion of a main body of a device, no knowledge is gleaned from applicant's disclosure. Further, as taught by Vargas et al, tension forces applied during the expansion of the main body of a device are changed into forces that bend extensions in a plane outside of a plane defined by the expansion (see figures 3-4; column 4, line 54 - column 5 line 19).

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Wijay (US Patent Number 6,203,569).

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN A. HOLLM whose telephone number is (571) 270-7529. The examiner can normally be reached on Monday - Friday 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAH/

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734